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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/809,901	03/26/2004	Hiraku Murayama	018961-068	7688

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BUCHANAN, INGERSOLL & ROONEY PC
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EXAMINER

HOEKSTRA, JEFFREY GERBEN

ART UNIT	PAPER NUMBER
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3736

NOTIFICATION DATE	DELIVERY MODE
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08/25/2008

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

ADIPFDD@bipc.com

Office Action Summary	Application No. 10/809,901	Applicant(s) MURAYAMA ET AL.	
	Examiner JEFFREY G. HOEKSTRA	Art Unit 3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 July 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4 and 7-14 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4 and 7-14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 26 March 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>6/24/08</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 07/24/2008 has been entered.

Notice of Amendment

2. In response to the amendment filed on 07/24/2008, amended claim(s) 1, 8, and 9 is/are acknowledged. The current rejections of the claim(s) 1-4 and 7-14 is/are *withdrawn*. The following new and reiterated grounds of rejection are set forth:

Information Disclosure Statement

3. The information disclosure statement(s) (IDS) submitted on 06/24/2008 is/are acknowledged. The submission is in compliance with the provisions of 37 CFR 1.97 and 1.98. Accordingly, the examiner is considering the information disclosure statement(s).

Claim Rejections - 35 USC § 102

4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

5. Claims 1-4 and 7-14 are rejected under 35 U.S.C. 102(b) as being anticipated by Chandrasekaran (US 6,093,157) as broadly as *structurally* claimed.

6. For claims 1-4 and 7-14, Chandrasekaran discloses a composite guidewire (22,80,82), comprising:

- a distal end portion (the right portion of the guidewire in Figure 1), a main body portion (the left portion of the guidewire in Figure 1), and an intermediate portion (the middle portion of the guidewire in Figure 1) disposed between the distal end portion and the main body portion;
- wherein said main body portion comprises: a center layer (34,60,78) comprising a first material comprising a NiTi based alloy (column 4 lines 3-5); a surface layer comprising a second, more rigid material comprising stainless steel (49,64) (column 2 line 59 – column 3 line 2 and column 5 lines 35-67); and (c) an intermediate layer (48) comprising a mixture of said first and second materials (column 4 line 66 – column 5 line 10) between said center and surface layers (as best seen in Figure 5);
- wherein said main body portion has a structure in which said center layer, said intermediate layer, said surface layer are structurally disposed in this order from a center of said main body portion toward an exterior of said main body portion (as best seen in Figure 5) (column 2 line 59 – column 3 line 2);
- wherein said distal end portion is formed of said first material, and is continuous with the center layer of said main body portion (as best seen in Figures 7-8);

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- wherein said intermediate portion comprises: the center layer (34,60,78) formed of the first material comprising a NiTi based alloy and an intermediate surface layer (48) formed of the mixture of said first material and said second material;
- wherein the mixture is decreased in the content of said first material toward said surface layer and increased in the content of said second material toward said surface layer such that a compositional gradually increasing gradient is formed in a radial direction (column 2 line 59 – column 3 line 2 and column 4 line 66 – column 5 line 10);
- wherein a weight ratio of the first to second material in the mixture is capable of being in the range of 1:9 to 9:1 and more specifically in the range of 3:7 to 7:3 because this ratio is inherently dependent upon material selection (as cited by Applicant, see Specification at least page 8 lines 1-4); and
- wherein said main body portion is capable of being formed by a sintered body, said sintered body having said center layer, said surface layer, and said intermediate layer, wherein said center layer is capable of being formed by sintering a powder of said first material, said surface layer is capable of being formed by sintering a powder of said second material, and said intermediate layer is capable of being formed by sintering a powder of said mixture of said first material powder and said second material powder.

Response to Arguments

7. Applicant's arguments filed 07/24/2008 been fully considered but they are not persuasive. Applicant argues the anticipatory rejection of the claims under Chandrasekaran, specifically arguing Chandrasekaran fails to disclose, teach, and/or fairly suggest "an intermediate layer comprising a mixture of said first material and said second material". The Examiner disagrees, maintains the rejection as broadly as structurally claimed, and in response notes the following:

8. In response to Applicant's argument, the Examiner reiterates Chandrasekaran discloses a composite guidewire comprising *inter alia*: an intermediate layer (48) comprising a mixture of first and second materials (column 4 line 66 – column 5 line 10) and disposed between the center layer and surface layer (as best seen in Figure 5), wherein said intermediate layer comprises: the center layer (34,60,78) comprised of a first material comprising a NiTi based alloy and an intermediate surface layer (48) formed of the mixture of said first material and said second material.

9. In addition the Examiner notes Applicant appears to rely heavily upon the terms "layer" and "mixture" as distinguishing limitations for patentability. Absent any special definitions in the instant Specification, the Examiner is treating the limitations "layer" and "mixture" on the merits with their plain dictionary meaning and broadest reasonable interpretation, such that "layer" may be defined as "a thickness of some material laid on or spread over a surface" and "mixture" may be defined as "a product of mixing, any combination or blend of different element, kinds, qualities, etc., or an aggregate of two or more substances that are not chemically united and that exist in no fixed proportion

to each other". As broadly as structurally claimed and under its broadest reasonable interpretation, "an intermediate layer comprising a mixture of said first material and said second material" is being plainly and reasonably interpreted for example to be at least an arbitrary or abstract thickness that is a combination of two different materials, or the like. Chandrasekaran clearly shows this in Figure 5.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JEFFREY G. HOEKSTRA whose telephone number is (571)272-7232. The examiner can normally be reached on Monday through Friday 8am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571)272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/J.H./

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Jeff Hoekstra

Examiner, Art Unit 3736

/Max Hindenburg/

Supervisory Patent Examiner, Art Unit 3736